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Effect of robot-assisted gait training on quality of life and depression in patients with hemiplegia

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Abstract

Aim: Robot-assisted gait training may affect functional activity,depression and quality of life in chronic stroke.In this study, we aimed to investigate the efficacy of robot-assisted gait training (RAGT) on quality of life and depression in patients diagnosed with hemiplegia due to an ischemic or hemorrhagic stroke.
Material and Methods: The study included 45 participants, including 19 chronic stroke cases in the intervention group (IG) (64.74±6.46 years) and 26 chronic stroke cases in the control group (CG) (63.88±8.76 years) who met the selection criteria. IG received RAGT in addition to conventional physiotherapy, while CG received only conventional physiotherapy. Patients were evaluated with the Functional Independence Measure (FIM), the Stroke-Specific Quality of Life Scale (SS-QOL) and the Beck Depression Inventory (BDI) before treatment, immediately after treatment (post-treatment), and three months after treatment (follow-up).
Results: Both post-treatment and third-month follow-up FIM scores significantly increased in IG (p=0.026 and p=0.011, respectively); however, there was no significant improvement in CG compared with the baseline values (p=0.180 and p=0.181, respectively). There was no significant difference in the SS-QOL scores for post-treatment and third-month follow-up measurements in either group compared with the baseline values (p= 0.856 and p= 0.349, respectively for IG and p= 0.545 and p= 0.186, respectively for CG). After treatment, BDI scores significantly improved in IG (p= 0.050), but there was no significant improvement in CG (p= 0.181) compared with the baseline values. The third-month follow-up BDI scores did not differ significantly in either group compared with baseline values (p = 0.156 for IG and p = 0.977 for CG).
Discussion: Robot-assisted rehabilitation,in addition to conventional physiotherapy, might be preferred to conventional physiotherapy alone in increasing patients' independence in self-care.

Keywords

Robot-Assisted Gait Training; Hemiplegia; Quality of Life; Depression

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Introduction

Stroke is a common serious and disabling healthcare problem throughout the world [1]. It is defined as an impairment of brain functions that causes sudden and rapidly developing clinical symptoms lasting more than 24 hours, or death. This is an important health problem that negatively affects the quality of life [2]. Rehabilitation of gait disorder after a stroke is one of the most important goals to increase functional activity, quality of life, and social participation [3]. Loss of muscle strength and balance are the most important causes of gait disturbance in stroke cases [4]. Robot-assisted therapy has been widely used for gait rehabilitation in several neurological disorders [5]. When combined with regular physiotherapy, it leads to further improvements in the mobility of stroke cases. Robot-assisted therapy devices provide autonomous training, where patients can engage in repeated and intense practices of goal-directed tasks leading to improvements in motor function [6]. There are various robot-assisted gait trainers to facilitate intensive walking training for people with a stroke, such as Lokomat® (Hocoma, Switzerland). Walking with the Lokomat® is accompanied by repetitive walking practices guided by a physiotherapist. This workstation device consists of a treadmill, a body weight support system, and bilateral exoskeletal components, which provide actuation at the hips and knees [7]. This has been found to improve walking functions in both acute-subacute and chronic periods in hemiplegic patients. Studies have found that patients whohave received robot-assisted gait training (RAGT) are more successful in independent walking than those who have undergone only conventional exercise therapy [8]. In a recent Cochrane review of 23 randomized controlled trials with 999 stroke patients, results showed that stroke patients who had received robot-assisted gait training in combination with physiotherapy were more likely to achieve independent walking than patients who had only received conventional gait training [9]. In another study with 56 stroke patients, robot-assisted therapy in combination with conventional physiotherapy produced greater improvement in gait function than conventional gait training alone [10]. In the post-stroke period, depression mood symptoms are very common. In addition, cognitive disorders occur in approximately 2/3 of the patients who have had a stroke. The presence of cognitive and psychological disorders has been correlated with reduced quality of life and poor socialization. Furthermore, it negativelyaffects rehabilitation prognosis [11]. RAGT has been reported to increase motivation and courage of patients [5]. It can also be stated that this treatment has a biofeedback effect, since patients are able to watch themselves on a screen when walking during RAGT. Therefore, it is hypothesized that RAGT may also affect depression and quality of life. There are various studies investigating the effectiveness of robotic rehabilitation in gait parameters, balance and functional status, but only a few studies have addressed its effectiveness in reducing depression. Thus, the aim of this study was to determine the effects of RAGT on functional activity, quality of life and depression in patients diagnosed with hemiplegia due to an ischemic or hemorrhagic stroke.

Material and Methods

This was a quasi-experimental study in which participants were assigned without randomizationto either the intervention group (IG) or control group (CG). All patients acknowledged their understanding and willingness to participate by providing signed consent. The study was conducted between April 2019 and January 2020 at Kutahya Health Sciences University Hospital, Turkey. This study was approved by the Ethics Committee of Kutahya Health Sciences University on March 18, 2019 (No:2019/02-7).

Participants

Recruitment and setting

Participants with hemiplegia who presented to the outpatient clinic of the Physical Medicine and Rehabilitation Department of Kutahya Health Sciences University Hospital during the study period were screened for eligibility by an independent physician and invited to participate in the study if found eligible. All participants were informed in advance about the procedures and assessments to be performed in the study, and those who agreed to participate signed consent forms.

Inclusion criteria

- Aged 18-75 years
- Diagnosed with hemiplegia due to cerebrovascular disease
- A history of hemiplegia at least six months ago
- Having a mini-mental test score above 21
- No hearing or vision problems
- Not taking any medication that could affect balance

Exclusion criteria

- Being uncooperative
- Having an additional systemic disease
- Having uncontrolled hypertension
- Presence of heart failure

Study procedures

After determining whether participants were to be included in IG or CG, the participants were evaluated by a blinded researcher (F.Y.), and then underwent four weeks of treatment applied by a different researcher (I.S.). Participants were reevaluated by the same blinded researcher (F.Y.) at the fourth week and again at the 12th week. The patients in IG received RAGT in addition to routine exercise therapy, while those in CG received only routine exercise therapy.

Interventions

Intervention group (RAGT in addition to conventional physiotherapy): The patients in IG received RAGT in addition to conventional physiotherapy.RAGT, the Lokomat® system of Robogait® was used. Body weight support was adjusted to a minimum without knee buckling or toe dragging. The walking speed was gradually increased up to 1.5 km/h [12]. In the first session, 50% body weight support was applied. After every walking session, the walking speed was readjusted to the patient's walking ability [13]. The device was placed on the patient, and then the patient's hip, knee, and ankle joint axes were consistently positioned with the exoskeleton orthosis to adjust joint movements in an individualized manner [14]. All patients in this group underwent 20 sessions of RAGT (45 minutes per session, five sessions per week for four weeks) in addition to 28 sessions of conventional physiotherapy (60 minutes per session, seven sessions per week for four weeks).

Control group (conventional physiotherapy only):The control

group received standard conventional physiotherapy. Physiotherapy sessions were focused on gait rehabilitation, such as exercising trunk stability, step initiation, and weight support on the paretic leg [13]. The program also included patient-specific neurofacilitation techniques, range of motion exercises, upper and lower extremity strengthening exercises to the anti-spastic muscles, motor skill training, and assistive device use training. All patients in this group underwent only 28 sessions of conventional physiotherapy (60 minutes per session, seven sessions per week for four weeks).

Outcomes

Data regarding the participants' age, gender, height, body weight, body mass index, duration, side and type of stroke, and educational level were recorded in a previously prepared assessment form during face-to-face interviews. The participants' functional status, quality of life and depression status were assessed using the methods described below. All the assessments were repeated before treatment, at four weeks (post-treatment), and at 12 weeks after treatment (follow-up) by the same physician (F.Y.) who was blinded to the interventions. Functional status was the primary outcome measure, whereas the quality of life and depression scores were the secondary outcome measurements.

Assessment of functional status

The functional status of the patients was evaluated with the Functional Independence Measure (FIM), which uses a scoring based on a seven-point scale (1: total assistance, 7: complete independence) in the categories of self-care, sphincter control, mobility, locomotor function, communication, and social perception. In the FIM, 13 items evaluate motor functions and five evaluate cognitive functions. The validity and reliability studies of the Turkish version of the scale were undertaken by Küçükdeveci et al. [15], who found it suitable for use in Turkish society.

Assessment of the quality of life

The Stroke-Specific Quality of Life Scale (SS-QOL) was used to evaluate the quality of life. This scale consists of 12 subscales containing 49 items to evaluate the quality of life of people diagnosed with a stroke. The items of SS-QOL are evaluated with a score ranging from 1 to 5. Higher scale scores indicate higher quality of life. Hakverdioglu et al. [16] showed that the Turkish version of SS-QOL was valid and reliable to measure the quality of life of patients with a stroke.

Assessment of depression

The depression levels of the participants were evaluated using the Beck Depression Inventory (BDI), consisting of 21 items, each offering at least four possible responses (0-3), ranging in intensity. According to the total scores obtained, 0-9 areconsidered normal, 10-19 are mild depression, 20-30 are moderate depression, and 31-63 are severe depression. The validity and reliability of the Turkish version of the BDI were shown by Ulusoy et al.[17].

Sample Size

The required sample size was calculated using G*Power software [18].Repeated-measures analysis of variance (ANOVA) with interaction within-between factors was used. The FIM score was the primary outcome measure. The effect size of FIM was estimated to be moderate (effect size = 0.25) for the group × time interaction intensity values in the study of Shahin et al [12]. For a statistical power of 0.80 and an α level of 0.05, it was estimated that a sample size of 36 participants (18 participants in each group) was necessary.

Blinding

The principal investigator was blinded to the group allocation during assessment and was not involved in the participants' treatment sessions or in data analysis process. The participants were asked not to mention their group to the researcher that performed the assessment (F.Y.).

Group Allocation

The group distribution was dependent on the participant's time of presentation to the physical therapy department. Participants who presented to the outpatient clinic between April and May 2019 were allocated in control group, and then all the consecutive patients were included in IG between June and July 2019 (Figure 1).

Statistical Methods

Statistical Package for the Social Sciences (SPSS, IBM, Armonk, NY, USA), version 21.0 was used for statistical analyses. Continuous variables are given as mean ± standard deviation values, and categorical variables as numbers (percentages). Analyses were conducted as per protocol. Intergroup comparisons of categorical variables were performed using the chi-square test. For the comparisons of the independent groups, the independent-samples t-test was used when parametric test assumptions were met, and the Mann–Whitney U test was used for non-parametric data. For the comparisons of the dependent groups, the repeated measures analysis of variance and the Friedman test were used.

Results

This study was completed with a total of 45 participants (25 males, 20 females), including 19 chronic stroke cases in IG (64.74 ± 6.46 years) and 26 chronic stroke cases in CG (63.88 ± 8.76 years). The participants' age, gender, height, body weight, body mass index, stroke duration, side of stroke, type of stroke and education levels are shown in Table 1 by group. In the comparison of the demographic data of the patients included in the study, no statistically significant difference was found except for weight (p=0.010).

Primary Outcomes

There were no significant differences between the groups in term of the FIM scores before treatment (96.31 ± 15.23 in IG and 86.26 ± 18.32 in CG, p = 0.510). Both post-treatment and third-month follow-up FIM scores significantly increased in IG (p = 0.026 and p = 0.011, respectively), but there was no significant improvement in CG (p = 0.180 and p = 0.181, respectively) compared with the baseline values. When the mean FIM values were compared between the two groups, there was a significant difference in favor of IG (p = 0.032) (Table 2).

Secondary Outcomes

There were no significant differences between the groups in relation to the SS-QOL scores before treatment (128.42 ± 20.94 in IG and 128.46 ± 23.7 in CG, p = 0.854). The post-treatment and third-month follow-up SS-QOL scores did not significantly differ in IG (p = 0.856 and p = 0.349, respectively) or CG (p = 0.545 and p = 0.186, respectively) compared with

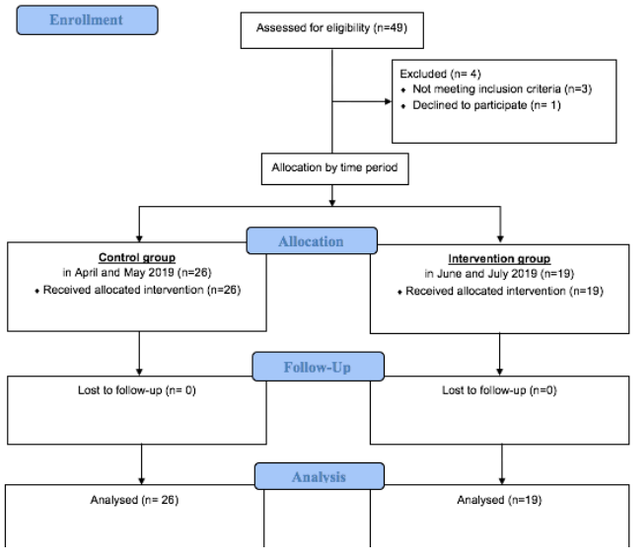

Figure 1. Flow Diagram

Table 1. Demographic characteristics of the groups

	Intervention Group (n=19) (Mean±SD)	Control Group (n=26) (Mean±SD)	p[1]
Age (years)	64.4± 6.46	63.88± 8.76	0.722
Height (cm)	166.68± 9.94	164.50± 9.66	0.444
Weight (kg)	80.42± 11.85	73.96± 13.18	0.010*
BMI (kg/m^2)	29.11 ± 4.64	27.20± 4.25	0.159
Duration of stroke (months)	30.63± 31.12	36.36± 25.67	0.504
Sex	n (%)	n (%)	
Male	11(57.9)	14 (53.8)	0.787
Female	8 (42.1)	12 (46.2)	
Side of stroke	n (%)	n (%)	
Left	10 (52.6)	8 (30.8)	0.218
Right	9 (47.4)	18 (69.2)	
Type of stroke	n (%)	n (%)	
Hemorrhagic	2 (10.5)	6 (23.1)	0.435
Ischemic	17 (89.5)	20 (76.9)	
Education	n (%)	n (%)	
Illiterate	3 (15.8)	4 (15.4)	0.488
Primary school	7 (36.8)	14 (53.8)	
Middle school	5 (26.3)	2 (7.7)	
High school	2 (10.5)	4 (15.4)	
University	2 (10.5)	2 (7.7)	

Cm: Centimeter, Kg: Kilogram, Kg/m2: Kilogram/Square Meter, N: Number of Participant, SD: Standard Deviation, %: Percentage, [1]: Chi square test, *: p < 0.05 for the comparison of changes from the baseline

the baseline values. There was also no significant difference between the meanSS-QOL scores of the two groups (p = 0.827) (Table 2).

No significant differences were observed between the groups in terms of the BDI scores before treatment (9.89 ± 4.56 for IG and 10.69 ± 5.08 for CG, p = 0.458). After treatment, the BDI scores significantly improved in IG (p = 0.050), but there was no significant improvement in CG (p = 0.181) compared with the baseline values. The third-month follow-up BDI scores did not significantly differ in either group compared with baseline values (p = 0.156 for IG and p = 0.977 for CG). There was also no significant difference between the mean BDI scores of the two groups (p = 0.704) (Table 2).

Discussion

The majority of previous studies in the literature examined the effectiveness of RAGT on walking capacity, speed and balance and reported RAGT to be an effective method to increase these parameters [19,20]. We hypothesized that these clinical effects of RAGT would also positively contribute to the quality of life, functionality and mood. In this study, we aimed to examine the potential functional and patient mood effects of Lokomat® training, which is based on computerized visual feedback known to increase patient output and motivation.

In the present study, both patient groups showed an improvement in FIM scores at the end of the treatment period, but the change was statistically significant only in IG. This result shows that robot-assisted rehabilitation might be a promising adjuvant therapy and could be superior to only conventional physiotherapy when combined with conventional physiotherapy in increasing patients' independence in self-care. In a previous study investigating the functional and psychological effects of robot-assisted therapy on 40 patients with spinal cord injury, a significant improvement was found in the quality of life scales and BDI scores compared to CG receiving only conventional therapy [12]. In another study involving 60 patients with spinal cord injury, a significant improvement was found in FIM and ambulation in the RAGT group compared to CG receiving only conventional therapy [21]. Improvement in the FIM scale, which evaluates self-care, sphincter control, transfer, communication, social participation, memory, and problem solving, continues until the third month, even if the patients are in the chronic period. This shows that RAGT does not only affect parameters related to walking, but it has a wider effect area covering functionality.

Table 2. Baseline, post-treatment and third-month follow-up outcome measures

Variables	Intervention Group			Control Group				
	Baseline	Post-treatment Δ (Mean ± SD)	Third-month Δ (Mean±SD)	Baseline (Mean±SD)	Post-treatment Δ (Mean ± SD)	Third-month Δ (Mean ± SD)	Mean differences in changes between the groups at the third month [95% CI]	p[3]
FIM	96.1± 15.23	1.27± 0.41* (p^2= 0.026)	1.99± 0.39* (p^2= 0.011)	86.26 ±18.32	0.89± 0.58 (p^2= 0.180)	0.90± 0.59 (p^2= 0.181)	1.05 [0.97;20.10]	0.032**
SS-QOL	128.42± 20.94	1.42± 5.13 (p^2= 0.856)	4.15± 3.97 (p^2= 0.349)	128.46± 23.79	1.11± 3.59 (p^2= 0.545)	2.88± 4.00 (p^2= 0.186)	1.22 [-9,26;11,72]	0.827
BDI	9.89± 4.56	-1.16 ± 0.58* (p^2= 0.050)	0.89± 0.63 (p^2= 0.156)	10.69± 5.08	-0.77 ± 0.60 (p^2= 0.181)	0.77 ± 0.98 (p^2=0.977)	0.479 [-3.00; 2.04]	0.704

FIM: Functional Independence Measure; SS-QOL: Stroke-Specific Quality of Life Scale, BDI: Beck Depression Inventory, SD: Standard Deviation, CI: Confidence Interval
Δ: Change from baseline, [2]: Mann–Whitney U test, [3]: Friedman test, *: p < 0.05 for the comparison of changes from the baseline, **: p < 0.05 for the group comparison

In our study, the post-treatment and third-month follow-up SS-QOL scores of IG and CG did not significantly differ. Many studies attempting to determine why early rehabilitation can provide better results have shown that it plays a major role in neural recovery and neuroplasticity [22,23]. Therefore, the lack of changes in the quality of life scores of our patients can be explained by the chronic period of the disease.

In our study, BDI significantly improved in IG, although there was no significant improvement in CG compared with the baseline values. Depression is a frequent complication of stroke, which worsens the course of post-stroke neurological disorders and decreases quality of life [24]. Consequently, it negatively affects the treatment and rehabilitation processes. A previous study found a relationship between walking distance and quality of life scores in patients with a stroke [25]. Another study investigating the relationship between disability and depression found depression to be associated with functional impairment after a stroke [26]. A case report showed a significant improvement in function, psychological and cognitive status after Lokomat® training in a chronic stroke case [5]. In our study, we considered that RAGT would increase the walking capacity and functional independence of stroke cases, which would, in turn, improve their quality of life and mood. However, we did not see any positive changes in BDI scores in our third-month evaluation. We also did not observe any superiority of RAGT compared to the conventional group depending on time. Although RAGT was effective immediately after treatment, it did not have any additional effect or superiority in the long term, which can be attributed to many factors in the patients' lives that could affect their mood during the three-month follow-up period.

The limitations of this study are the lack of randomization in patient grouping, no questions about the patients' dominant extremity or the presence of neglect syndrome, and a short follow-up period of three months.

Conclusion

Many previous studies have described the efficacy of RAGT in improving motor and ambulatory function in patients with a stroke. In our study, we considered that RAGT would improve walking capacity and functional independence in chronic stroke cases and consequently lead to an improvement in their quality of life and mood. Both patient groups showed improvements in FIM at the end of the treatment period, but the change was statistically significant only in IG that had received RAGT. This result shows that RAGT, in addition to conventional physiotherapy might be preferred to conventional physiotherapy alone to increase patients' independence in self-care.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflict of interest

None of the authors received any type of financial support that could be considered potential conflict of interest regarding the manuscript or its submission.

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